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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,565

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Suresh Pareek

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EXAMINER

CHAN, HENG M

ART UNIT

PAPER NUMBER

1795

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,565	<b>Applicant(s)</b> PAREEK ET AL.	
	<b>Examiner</b> HENG M. CHAN	<b>Art Unit</b> 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. Applicant's amendments and remarks filed 3/9/2010 have been acknowledged. Claims 1-14 are pending. Of these claims, claims 1-9 and new claims 11-13 belong to an elected group (Group I) and are under consideration. Claim 10 is withdrawn from consideration as a non-elected group (Group II). Newly submitted claim 14 is drawn to a pharmaceutical oral solid dosage form (Group III) that is independent or distinct from the invention of the originally elected (Group I) for the following reasons:

The inventions listed as Groups I through III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature shared by each invention is the ready mix flavored composition comprising a polymer and a flavoring agent. This technical feature, however, fails to define a contribution which each of the inventions, considered as a whole, makes over the prior art. A review of US 2002/01320006 to Sue et al. makes clear that the inventions of the groups I through III lack the same or corresponding special technical feature because the cited reference discloses a coating composition in a color coat comprising a polymer and a flavoring agent (see rejection below). Accordingly, the prior art of the record supports restriction of the claimed subject matter in to the groups as mentioned immediately above.

Since Applicant has received an action on the merits of the originally presented invention (a ready mix flavored composition), this invention has been constructively

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elected by original presentation for prosecution on the merits. Accordingly, claim 14 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The previous objections to the specification and claims and the rejections under 35 USC § 112, second paragraph, and 102(b) have been withdrawn as a result of Applicants' amendments and further consideration. The following new grounds of rejections are being made after further consideration of the claims and the reference.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites "non-soluble additives and a colorant" in line 2. However, the 4<sup>th</sup> paragraph of the 6<sup>th</sup> page in the specification, after amendment, clearly indicates that colorants are non-soluble additives. It is unclear whether the instant claim requires both a colorant and non-soluble additives other than a colorant. For examination purposes, the instant claim is interpreted to require non-soluble additives which may be a colorant.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –  
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**3. Claims 1-6 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 2002/01320006 to Sue et al.**

Regarding claim 1, Sue et al. teach a color coat comprising a polymer, e.g. hydroxypropyl methylcellulose, and a flavoring agent, e.g. peppermint oil or other flavorant ([0088-89]). The lack of mention of a sweetening agent is understood that the composition does not comprise a sweetening agent. The color coat itself or the composition of the color coat prior to application reads on the claimed ready mix flavored composition and the color coat composition must be capable of masking the unpleasant taste of a solid core because the ingredients are the same. The limitation “for film coating of pharmaceutical oral solid dosage form” is a recitation of intended use and does not necessarily impart structural or compositional limitations on the composition. In case it does, Sue et al. teach that all coatings can be applied using conventional film coating technology well known in the pharmaceutical industry, for example, film-coating ([0036]), onto a pharmaceutically active tablet core **2** (abstract; Fig. 1). That is, the composition can be used for film coating of pharmaceutical oral solid dosage form.

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Regarding claims 2 and 11, Sue et al. teach that the color coat comprises hydroxypropyl methylcellulose ([0089]), a water soluble hydrophilic polymer.

Regarding claims 3 and 12, Sue et al. teach that the color coat comprises ethylcellulose ([0089]), a water insoluble hydrophobic polymer.

Regarding claims 4 and 13, Sue et al. teach that the color coat comprises ethylcellulose in addition to hydroxypropyl methylcellulose ([0089]), a combination of a water soluble hydrophilic polymer and a water insoluble hydrophobic polymer.

Regarding claim 5, Sue et al. teach peppermint oil as a flavoring agent ([0089]). This flavoring agent is volatile.

Regarding claim 6, Sue et al. teach that the color coat comprises a plasticizer, e.g. polyvinyl alcohol, a colorant, e.g. titanium dioxide, which is also a non-soluble additive ([0090]).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sue et al. as applied to claim 1 above, in view of US 5,098,715 to McCabe et al.**

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Regarding claims 7-9, Sue et al. teach that the color coat comprises a polymer, e.g. hydroxypropyl methylcellulose ([0089]), a plasticizer, and non-soluble additives such as a colorant ([0090]).

Sue et al. do not expressly teach that the polymer comprises the claimed amounts of polymer, flavoring agent, plasticizer, and non-soluble additives selected from a group consisting of colorants, detackifiers and opacifying agents.

McCabe et al., who also relate to flavored film-coated tablet, teach using about 5 to 95% w/w hydroxypropyl methylcellulose, 0 to about 25% w/w polyethylene glycol (a plasticizer), 0 to about 20% w/w titanium dioxide or colorant, and 2.0% w/w natural and artificial peppermint flavor, based on the total weight of the coating composition (column 4, lines 41-55; Example 2).

It would have been obvious to one of ordinary skill in the art at time of invention to have arrived at the claimed amounts of polymer, flavoring agent, plasticizer, and non-soluble additives such as colorants in the composition of Sue et al. based on McCabe et al., motivated by the fact that McCabe et al. teach that the preferred flavoring amount is readily determined by balancing the goal of adding an amount sufficient to mask the core tablet taste and provide a distinct, characteristic and pleasing taste, and the goal of keeping the tablet from being too much like a candy or mint product. The desired strength of the flavoring may vary depending on the type of tablet and the intended recipients and the identity of the flavoring (column 5, lines 11-19). The skilled artisan would have therefore optimized the amounts of the ingredients in the composition in order to achieve the desired strength of flavoring.

***Response to Arguments***

6. Applicants' arguments filed 3/9/2010 have been fully considered but they are not persuasive. Applicants argued about the negative limitation in the independent claim, reciting, "without a sweetening agent." The Examiner has relied on Sue who teaches a color coat comprising a polymer and a flavoring agent, but not a sweetening agent. The color coat itself or the composition of the color coat prior to coating reads on the claimed invention. Although Sue teaches using sweetening agents in the second coating compartment, the Examiner is not relying on that coating compartment to make the rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HENG M. CHAN whose telephone number is (571)270-5859. The examiner can normally be reached on Monday to Friday, 9:00 am EST to 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer K. Michener can be reached on (571)272-1424. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer K. Michener/  
Supervisory Patent Examiner, Art Unit 1795

/HENG M CHAN/  
Examiner, Art Unit 1795